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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/680,284	10/06/2000	Sigrid Lise Fossheim	REF/FOSSHEIM/100	8494
7590 03/24/2004				
Bacon & Thomas PLLC 625 Slaters Lane 4th Floor Alexandria, VA 22314-1176			EXAMINER WELLS, LAUREN Q	
			ART UNIT 1617	PAPER NUMBER

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/680,284

**Applicant(s)**

FOSSHEIM ET AL.

**Examiner**

Lauren Q Wells

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,6,9-11,24-26,31-37 and 39-68 is/are pending in the application.
- 4a) Of the above claim(s) 1-3,6,9-11,24-26,31-36,39-49,56-60,65 and 68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 37,50-55,61-64,66 and 67 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1-3, 6, 9-11, 24-26, 31-37, 39-68 are pending. Claims 1-3, 6, 9-11, 24-26, 31-36, 39-49, 56-60, 65, and 68 are withdrawn from consideration, as they are directed toward non-elected subject matter. The Amendment filed 11/13/03, amended claims 37 and 68.

The Applicant's arguments toward the phrase "tissue electrical activity" and the state of the art are persuasive to overcome the 35 USC 112 rejection over this phrase in the previous Office Action. The Applicant's amendment to claim 37 is sufficient to overcome the 35 USC 112 rejection over this claim in the previous Office Action.

### ***Election/Restrictions***

Applicant states, "Applicants further note that claims 56-60, 65 and 68 have been mistakenly referred to as 'withdrawn from consideration'. . . Consideration thereof is respectfully requested". This argument is not persuasive. The Examiner respectfully points out that these claims are withdrawn from consideration per the election of species requirement. See page 3 of the previous Office Action mailed 5/15/03.

This Election/Restriction Requirement is hereby made final.

### ***103 Rejection Maintained***

The rejection of claims 37, 50-55, 61-64, 66-67 under 35 U.S.C. 103(a) as being unpatentable over Gamble et al. (4,728,575) in view of Ozer et al. (Eur. J. Pharm. Biopharm.) is MAINTAINED for the reasons set forth in the Office Action mailed 5/15/03, and those found below.

Applicant argues, "Gamble is concerned with providing a formulation of micelles and paramagnetic material that simultaneously maximizes micelle stability while permitting adequate

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rate of water exchange across the membrane. . .Gamble does not contain any motivation to modify the micelles in such a way that they respond to a physiological parameter like for instance temperature or pH. Such a modification is neither explicitly nor implicitly mentioned in the disclosure of Gamble”. This argument is not persuasive. First, it is respectfully pointed out that the instant claims are directed toward a composition and not toward a method of modification. Second, it is respectfully pointed out that Gamble et al. teach micellular particles of the same phospholipids as taught by the instant invention. Thus, while Gamble may not explicitly state that their particles are temperatures/pH sensitive, such a sensitivity is a property of the particles, as evidenced by the teachings of Ozer et al.

Applicant argues, “Ozer et al., meanwhile describe temperature and pH sensitive liposomes used in drug delivery. Ozer is completely silent about contrast agents or diagnostic agents encapsulated in such liposomes”. This argument is not persuasive. First, it is respectfully pointed out that Stedman’s Medical Dictionary defines a drug as a therapeutic agent; any substance, other than food, used in the prevention, diagnosis, alleviation, treatment, or cure of disease. It is respectfully pointed out that a contrast/diagnostic agent is a substance used in the diagnosis and treatment of a disease. Second, it is respectfully pointed out that both Gamble et al. and Ozer et al. are directed toward liposomes that encapsulate active agents for in vivo administration, wherein the active agents are released in vivo. Thus, Gamble et al. and Ozer et al. are directed toward the same field of endeavor and there is motivation to combine the references.

Applicant argues that there is no motivation to combine the teachings of Gamble et al. and Ozer et al. See the above paragraph for a response to this argument.

Applicant argues that the Examiner has inappropriately combined the references via an “obvious to try” standard. This argument is not persuasive. As discussed in the previous Office Action, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify or teach the liposomes of Gamble et al. as being temperature sensitive because of the expectation of achieving a liposome that exhibits controlled release in a site-specific manner.

Applicant argues, “any modification of Ozer to thereby prevent the liposome membranes from being destroyed would be against the implicit teaching of Ozer. As the Examiner’s combination of Ozer with Gamble would destroy the invention of Ozer, i.e., prevent drug delivery”. This argument is not persuasive. First, it is respectfully pointed out that the teachings of Ozer are NOT directed to preventing drug delivery, but are directed toward promoting drug delivery in a controlled fashion. Second, it is respectfully pointed out that both Gamble et al. and Ozer et al. are directed toward liposomes that degrade in vivo in order to release the active agents contained within the liposomes.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is 571-272-0634. The examiner can normally be reached on M&R (5:30-4).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

lqw

  
**SREENI PADMANABHAN**  
SUPERVISORY PATENT EXAMINER